UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,020	10/12/2001	Alan J. Magill	P66822US0 (WRAIR 98-40/46	7596

53502 7590 06/08/2006

OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)
U.S. ARMY MED. RESEARCH & MATERIAL COMMAND
504 SCOTT STREET
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
FORT DETRICK, MD 21702-5012

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,020	MAGILL ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,12,22-25 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The response and amendment filed 4-19-06 have been entered into the record. Claims 4, 11, 12, 22-25, 29, 30 and 32 are pending and under examination. Claims 1-3, 5-10, 13-21, 26-28 and 31 have been cancelled.

The text of Title 35 of the US Code can be found in the previous office action of record.

Rejections/Objections Withdrawn

The objection to the specification as lacking antecedent basis in the specification for the term "free of dextran" is withdrawn in view of Applicant's response and arguments.

Rejections/Objections Maintained

The rejection of claims 4, 11, 12, 22-25, 29, 30 and 32 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained in part for reasons made of record in the Office Action mailed 1-23-06.

Applicant's arguments have been carefully considered but are not fully persuasive. Applicant indicates that the specification indicates that the microfluidized extract was reformulated to remove dextran because dextran caused transient urticaria in the control and as such a microfluidized lysate preparation free of dextran does have support in the specification as filed. This is found persuasive.

Applicant also argues that the false positive hypersensitivity reaction of claim 1 refers to the hypersensitivity to dextran as experienced by the subject of Example 3. This is not persuasive, the claim recites "hypersensitivity reaction" not transient urticaria that is strictly limited to type I hypersensitivity. This is also not persuasive, because this is not what the claims state. The structure of the claim specifically recites that it is the microfluidized lysate that does not cause a false positive hypersensitivity reaction when administered to a subject. This is not in relation to the control; it is in relation to the

lysate preparation per se. Applicant has not conceived that the lysate preparation as claimed, does not cause false positive hypersensitivity reactions (types I-IV) or type I specifically. The claim is not viewed as limited to transient urticaria due to dextran in a control. Applicant's arguments are inconsistent with the structure and limitations of the claims. Further, the specification as filed does not support false positive hypersensitivity reactions due to other factors and other microfluidized components or diluents. Therefore, the relied upon composition of the specification of Example 3, is not commensurate with the claims. This part of the rejection is maintained for reasons made of record.

Claims 4, 30 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirement 1 and 2, 1994 and 1995).

Applicant's arguments have been carefully considered but are not persuasive. Applicant argues that the Examiner relies upon the last line of Rowton et al (1996) out of context. Applicant argues that it is unclear what products Rowtan et al tested and under what conditions and that the testing was done in guinea pigs and not human subjects. This is not persuasive; the testing of Rowton et al explicitly teaches that the tested products of the prior art did not provide inappropriate response in naïve guinea pigs. No responses in this context of naïve animals indicated that no type I-IV responses were seen with the lysate. This is absolutely clear. This is the ultimate control for false positives, the lysate preparation in naïve animals. The claim requires that the lysate provide no false positive reactions and the naïve animals did not have any reaction at any dose level and therefore, no hypersensitivity reactions were observed. No reaction to the controls is the preeminent finding for a lack of false positives in naïve (non-exposed subjects). Applicant merely speculates. The statement of the art, is clear an unequivocal. No response in naïve (non-exposed) guinea pigs. Applicant argues that it is well known in the art that the

animals and humans exhibit different hypersensitivities to a plurality of compounds. This is not persuasive, the claims are not limited to reactions in humans and applicant has not established on the record that dextran does not cause under any circumstances hypersensitivity reactions in guinea pigs. Applicant argues the statement that the properties of the compositions of the prior art are inherent, is incorrect because Example 3 teaches that the statement is incorrect because a prior art microfluidized preparation was tested and did in fact cause a false positive reaction. This is not persuasive, the issues is the products of the cited art not some other product tested in the specification. Applicant argues that the explicit properties are not disclosed. This is not persuasive; the properties are inherent to the preparations, in view that no hypersensitivity reactions were seen in naïve animals. Applicant has provided no testing of the cited prior art products to obviate this rejection. Applicant argues that the reference do not explicitly teach the properties. This is not persuasive, inasmuch as the functional property of the prior art is met, so is the free of dextran. Applicant argues that the references are non-enabling, because the art does not teach which ingredients in the lysate preparation may or may not be responsible for causing false positive sensitivity reactions. This is not persuasive, the art is enabling because it teaches how to make and test the product. Applicant has previously argued the skill in the art is high, one of skill of course knows how to microfluidize the parasites in any buffer and therefore the disclosure of the prior are is sufficient to make the lysate preparation. The prior art made and tested the lysate preparation. The product is inherently anticipated. Therefore, the rejection is maintained.

Claims 4, 29, 30 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stitler et al (47th Annual meeting of the ASTM&H, San Juan, PR, 1998).

Applicant consolidated and argued this rejection for the same reasons as the 102(b) rejection set forth above. Applicant's arguments are not persuasive for the reasons set forth *supra*.

Claims 11, 21, 22-25 stand rejected under 103(a) as being unpatentable over Leishmania Research project DOD-8B, or Stitler et al (Production of Leishmania Skin Test GMP Protocol requirement 1 and 2, 1994 and 1995) or Stitler et al (47th Annual meeting of the ASTM&H, San Juan, PR, 1998) each taken in view of Reed (US 2002/0169285).

Applicant's arguments have been carefully considered but are not persuasive for the following reasons. Applicant argues that since the references under 102(b) fall, so does the rejections under 103. This is not persuasive because the rejections under 102(b) are maintained for reasons made of record. Even should the rejections under 102(b) fall, the claims would still be rejected under 103 because Reed et al specifically teach that pharmaceutical formulation of lysed preparations include a saline solution with appropriate preservative such as phenol and/or Tewen80™. As such, Applicants arguments are not persuasive. Further, the art of Reed et al teaches that this is conventional formulation of lysates for skin testing, which do not include dextran.

Status of the Claims

All pending claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645